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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,278	09/11/2003	William J. Carroll	000309-00049	5691
27557	7590	01/18/2006		
BLANK ROME LLP 600 NEW HAMPSHIRE AVENUE, N.W. WASHINGTON, DC 20037			EXAMINER KRAMER, NICOLE R	
			ART UNIT	PAPER NUMBER
			3762	
DATE MAILED: 01/18/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,278

Applicant(s)

CARROLL ET AL.

Examiner

Nicole R. Kramer

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3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/3/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because the photographs of Figs. 1 and 2 are too dark and cannot be read. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 17 is objected to because of the following informalities: a typographic error appears in the word "comprising." Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 5-6, 10, 11-12, 14-15, 20-21, 24-25, 29, 30-31, and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,273,033 ("Hoffman").

Hoffman discloses an electro-medical device that applies surface electrical stimulation to a body segment having a joint (Hoffman discloses a method and electrical stimulator apparatus for the treatment of osteoarthritis). Examiner notes that the recitations "for improving synovial fluid" (located in preamble of claim 1), "method of improving synovial fluid" (located in the preamble of claim 11), "for delaying onset of arthritis" (located in the preamble of claim 20), and "method of treating arthritis" (located in the preamble of claim 30) each occur in the preamble of the independent claims. **The recitations have not been given patentable weight because the recitations occur in the preambles.** A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where

the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In addition, with respect to the apparatus claims 1-10 and 20-29, Examiner notes that recitations of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. For example, claims 1 and 20 currently read on every prior art electrotherapy device that applies surface electrical stimulation to the body because they are capable of “improving synovial fluid at a body segment having a joint” and capable of “delaying onset of arthritis at a body segment having a joint.”

With respect to claims 2, 12, 21, and 31, Hoffman discloses transcutaneous electrical nerve stimulation.

With respect to claims 5, 14, 24, and 33, Hoffman discloses that the electrical stimulation imparts to the body segment at the joint (electrodes are placed on the knee as shown in Fig. 4; see col. 6, lines 5-12).

With respect to claims 6, 15, 25, and 34, Hoffman discloses that the electrical stimulation is applied continuously (Examiner notes that “continuously” encompasses the treatment program disclosed in Hoffman in which patients maintained the electrical stimulating therapy for a eight week interval; see col. 5, line 60 - col. 6, line 4).

With respect to claims 10 and 29, Hoffman discloses that patients were instructed to use the device 6-10 hours per day (see col. 6, lines 13-20), but Examiner notes that the device is capable of applying the electrical stimulation for only 10 minutes to 4 hours per day.

5. Claims 1-13, 15-16, 19-32, 34-35, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,324,317 ("Reiss").

Reiss discloses an electro-medical device that applies surface electrical stimulation to a body segment (Reiss discloses a portable inferential stimulator for reducing pain). Examiner notes that the recitations "for improving synovial fluid" (located in preamble of claim 1), "method of improving synovial fluid" (located in the preamble of claim 11), "for delaying onset of arthritis" (located in the preamble of claim 20), and "method of treating arthritis" (located in the preamble of claim 30) each occur in the preamble of the independent claims. **The recitations have not been given patentable weight because the recitations occur in the preambles.** A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

With respect to claims 2, 12, 21, and 31, Reiss discloses interferential stimulation.

With respect to claims 3 and 22, Reiss discloses that the interferential stimulation generates a current with a resultant beat frequency from 0-250 Hz (the resultant beat frequency preferably ranges from 1-150 Hz; see col. 1, lines 49-60 which explains that an interference generation means generates a selected frequency from about 1,000 Hz different from the fixed frequency, preferably 1 to 150 Hz greater than the fixed frequency, to produce a beat frequency equal to the different in the two generated frequencies).

With respect to claims 4, 13, 23, and 32, Reiss discloses that the interferential stimulation generates an alternating current with a base medium frequency of at least 1 KHz but no more than 20 KHz (see col. 1, lines 49-60 which explains that the fixed frequency generation means generates a fixed frequency from about 1,000 to 20,000 Hz).

With respect to claims 5 and 24, Reiss is capable of imparting electrical stimulation to the body segment at the joint.

With respect to claims 6, 15, 25, and 34, Reiss discloses continuous electrical stimulation (the stimulator may operate in a continuous manner in a first mode of operation; see col. 1, lines 62-67).

With respect to claims 7, 9, 16, 26, 28, and 35, Reiss discloses that the electrical stimulation is within a range of 0.1 mA to 150 mA (the preferable output amperage varies from about 0 to 50 milliamps; see col. 2, lines 18-26).

With respect to claims 8 and 27, Reiss is capable of applying the electrical stimulation having characteristics and sequencing which mimics normal electrical

sequencing of surrounding muscles of the joint during normal functioning activity because the inferential stimulator includes a mode control to permit changing the sequence of stimulation to find the most effective pain relief (see col. 1, line 62 - col. 2, line 17).

With respect to claims 10, 19, 29, and 38, Reiss discloses that the electrical stimulation includes a duration from 10 minutes to 4 hours per day (treatments of up to about 60 minutes are preferred; see col. 2, lines 20-26).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 17-18 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,324,317 ("Reiss"), as applied above, in view of U.S. Patent No. 5,350,415 ("Cywinski").

As described above, Reiss discloses a portable inferential stimulator for reducing pain, reducing edema and inflammation, increasing blood flow, and reducing muscle spasms (see Abstract). Reiss discloses that the inferential stimulator includes a mode control to permit changing the sequence of stimulation to find the most effective pain relief (see col. 1, line 62 - col. 2, line 16). Reiss fails to specifically disclose a mode of operation in which the electrical stimulation is applied having characteristics and

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sequencing which mimic normal electrical sequencing of surrounding muscles of the joint during normal functioning activity. Cywinski teaches that it is known in the art to apply electrical stimulation that emulates natural electrical sequencing of muscles in order to provide functional and structural trophic changes in the muscle (see col. 3, lines 8 - 69). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the sequence of stimulation of the inferential stimulator disclosed in Reiss such that the sequence of stimulation mimics normal electrical sequencing of surrounding muscles of the joint during normal functioning activity in order to provide functional and structural trophic changes in the muscle while simultaneously providing pain relief.

With respect to claims 18 and 37, Reiss discloses that the electrical stimulation is within a range of 0.1 mA to 150 mA (the preferable output amperage varies from about 0 to 50 milliamps; see col. 2, lines 18-26).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 3,881,494 ("Paul, Jr.") teaches a TENS device for treating arthritis.

U.S. Patent No. 3,902,502 ("Liss et al.") teaches a TENS device for treating arthritis.

U.S. Patent No. 5,817,138 ("Suzuki") teaches a multi-channel, interferential wave, micro-current device for treating a variety of conditions, including rheumatoid arthritis.

U.S. Patent No. 5,947,913 ("Palumbo") teaches a method and system which utilizes muscle stimulation and TENS to treat a human knee.

"Direct Electric Acupuncture for Patella Chondromalacia: A Preliminary Report of a Clinical Study," Hua Gu, *Acupuncture Today*, October 2001, Volume 2, Issue 10 teaches that electrical stimulation may change the viscosity and pH of a joint's synovial fluid to alter the irritation to the synovial membrane.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NRK

1/6/2006


George Manuel
Primary Examiner